Brown and Williamson Website

HOT TOPICS Smoking and Health Issues

Preface

On occasion Brown & Williamson is asked to clarify its position on smoking and health issues. Others may also, from time to time, attempt to characterize our views on smoking and health, and this characterization may not always be accurate. We are, therefore, issuing these statements to make clear where we stand and to explain the basis for our position on these issues. Nevertheless, Brown & Williamson believes that smokers should rely on the advice of appropriate health authorities such as the Surgeon General for information on smoking and health, including the conclusions that smoking causes disease and is addictive.

Smoking and Disease

Brown & Williamson believes that people who choose to smoke are accepting significant health risks, and that, in the most simple and commonly understood sense, smoking is the cause of certain diseases.

Deciding whether or not smoking causes disease in groups of people involves comparing the evidence that is available with a set of 'criteria for causation' laid out by the U.S. Surgeon General and others, which cover both statistical and non-statistical evidence. It is then necessary to make a judgment about whether the evidence fits the criteria. In our view, it is appropriate to make judgments about the health effects of smoking primarily upon statistical evidence when the objective of the assessment is to shape public health policy concerning tobacco use. Epidemiological (statistical) studies of cigarette smoking and various diseases show that groups of smokers have a significantly increased incidence of those diseases compared to nonsmokers. The strength of the reported risks varies from one disease to another, from one population to another and with the amount smoked. The percentage of smokers developing diseases like lung cancer also varies between different populations. Nevertheless, for certain diseases, including lung cancer, studies in the U.S. and elsewhere indicate that the risks are strong and consistent. This suggests that smoking is a cause of (or a contributor to) disease in humans. However, we know of no way to verify that smoking is a cause of any particular person's adverse health or why smoking may have adverse health effects on some people and not others. Warning the public is a primary objective of public health authorities, and the available evidence - in particular, the strength of the statistical evidence - is sufficient for them to make the judgment that smoking causes disease. If the judgment is based on statistical criteria, we agree that the evidence is sufficient to determine that smoking causes disease. Therefore, Brown & Williamson believes it is appropriate for the public health community to conclude and warn the public that cigarette smoking causes certain diseases. On the other hand, as a manufacturer of cigarettes, the role of Brown & Williamson is very different from that of public health authorities. Our objective in analyzing the evidence on smoking and disease is to understand our product better and to do the best we can and aim to produce a less hazardous product even with the uncertainties that exist on exactly what constitutes a less hazardous product. Given this objective, we place greater emphasis on experimental (non-statistical) evidence than is required for public health authorities as this is the best source of information to provide us with practical guidance on how to modify our products to reduce the risks of smoking. While much is known about the health risks of cigarette smoking, there is no consensus among scientists about how exactly smoking might contribute to disease. Ultimately it is the biological sciences, rather than medical statistics, which will make the major contribution to this knowledge. Despite years of research, there remain significant gaps in understanding including:

PM3003572359

- the role of individual smoke constituents in contributing to smoking-related disease in humans
- the role that various cigarette design and formulation parameters may have in decreasing or increasing the risks of smoking
- which experimental toxicological tests of cigarette smoke are predictive of effects of cigarette smoke in humans
- the fundamental mechanisms of how cigarette smoking might contribute to human disease.

These information gaps have resulted in several limitations of what we as a manufacturer of cigarettes are able to accomplish. By identifying these and other uncertainties in the existing science, we are not attempting to deny that smoking causes disease. Rather, we are identifying the limitations of what we are capable of achieving in producing a product acceptable to smokers with modifications that might reduce the risks associated with smoking. Despite decades of research internally and externally, we do not know what modifications could be made to cigarettes to make them both safer and acceptable to consumers. Furthermore we do not yet know how to verify scientifically whether any particular cigarette modification, in fact, results in a product that is safer. Although statistical studies can be used to assess whether particular product trends (e.g. the move to lower tar cigarettes) are associated with reduced risks of disease, it can be 20 years or more before such results become available. Also, it is difficult to use such studies to differentiate between different brands or products because of the difficulty in finding people who stick with a particular brand or product over a period of time that would be long enough to be expected to impact on disease development. (See Brown & Williamson's Research into Less Hazardous Cigarettes).

The difference in emphasis on the importance of experimental evidence on smoking and disease between ourselves as a manufacturer of cigarettes and public health authorities leads to accusations that somehow we are seeking to deny that smoking causes disease. This is not the case. The strength of the statistical evidence and lack of an alternative explanation for the increased risk of disease in groups of smokers, coupled with the fact that the experimental evidence does not refute the conclusion that smoking causes disease, leads Brown & Williamson to concur on public health grounds that the best judgment is that smoking is a cause of certain diseases.

We recognize that on the state of the experimental evidence, others may reach different judgments. We agree that it is reasonable for scientists to believe that knowledge of a causal mechanism or proof through an appropriate experimental model is required to establish causation. Brown & Williamson's judgment has been reached after careful and thorough assessment and reflects the weight of the accumulated information. It does not reflect any specific study or development.

Brown and Williamson's Research into Less Hazardous Cigarettes

From the mid-1950's to the present, B&W has conducted internal research, on its own, and through BAT-affiliated companies into development of cigarettes that might lead to a reduced risk. Our efforts have taken into account suggestions and recommendations from the external scientific community and we have collaborated with regulatory authorities in the U.S. (through the Tobacco Working Group under the auspices of the National Cancer Institute) and the U.K. (through the Independent Scientific Committee on Smoking and Health). The various strategies pursued have included the following:

- General reduction of smoke yields through filtration and ventilation.
- Identification of cigarette design and formulation parameters that could be changed to reduce biological activity as measured in a variety of toxicological tests.
- Modification of cigarette design and formulation parameters to bring about reductions in specific tobacco smoke constituents regarded by the scientific community as possibly important to the contribution to smoking-related human disease
- Heating rather than burning tobacco.
- Alteration of cigarette smoke nicotine to "tar" ratio such that the cigarette would deliver normal nicotine levels at a reduced "tar" level.

Research into many of the same areas has also been conducted over the years by the external scientific community. While much is known about product modification and the health risks of cigarette smoking, we still do not know how smoking might contribute to disease. Neither our research nor that of the external scientific community has provided unequivocal and certain guidance about what modifications could be made in cigarettes to reduce the risk of smoking.

Despite years of research, there remain significant gaps in our understanding concerning:

- the role of individual smoke constituents in contributing to smoking related disease in humans.
- The role of various cigarette design and formulation parameters in contributing to smoking related disease in humans
- which experimental toxicological tests of cigarette smoke are predictive of effects of cigarette smoke in humans.
- The fundamental mechanisms of how cigarette smoking might contribute to human disease

These information gaps have resulted in several limitations of what we as a manufacturer of cigarettes are able to accomplish. We do not yet know with certainty what modifications could be made to cigarettes to make them safer. Furthermore, we do not yet know how to verify scientifically whether any particular cigarette modification, in fact, results in a product that is safer. Lack of consumer acceptance of many alternative cigarette designs has resulted in significant limitations in the range of modifications that are feasible. Finally, we know of no cigarette modification, which if made, would receive clear endorsement from the scientific and/or public health community as reducing the risks of smoking.

In light of these uncertainties, we have focused the majority of our efforts on general reductions of the smoke yields of cigarettes. This approach received support from the Surgeon General in the form of advice to smokers who were not willing to quit, that they should switch to lower-tar cigarettes. This advice was based on the results of studies suggesting that the switch that began in the late 1950s from non-filter to filter products may have been associated with reductions in the risk of lung cancer (though not necessarily for other smoking-associated diseases). However, the Surgeon General stated in a number of reports (e.g., 1981, 1989) that it was not possible to draw the same conclusions for current low tar products.

It is still too early to be sure what the risks of disease may be for those who have predominantly smoked modern lower tar products compared to those who have smoked higher tar products. While it might be expected that risks of disease in smokers might decrease with decreasing tar deliveries, a number of scientists and health authorities have

suggested that other factors associated with the development of modern low tar cigarettes may cancel out any benefits that may be expected to occur as a result of the lower tar. The factors listed by health authorities include changes in smoking behavior (e.g., the phenomenon of compensation) and product design features used to reduce the tar in today's products (e.g., increasing ventilation).

Although the move to lower-tar cigarettes, like others, also has uncertainties, it is the one that has received the greatest amount of encouragement from the external scientific and public health communities, and has been most successful from the perspective of consumer acceptance. In some countries around the world — in particular, for example, in the United Kingdom — governments have generally been more supportive of the continuation of low yield programs. Despite concerns about whether, and the extent to which, low yield cigarettes may reduce the risks associated with smoking, public health authorities in many countries around the world continue to set ceilings for tar levels in products in their markets. This suggests that, in the absence of an alternative direction indicated by the science on smoking and health, and until more definitive epidemiological evidence becomes available on whether reduced risks are associated with smoking modern low tar products, many health authorities appear to be making the assumption that reduction of yields remains an appropriate strategy to follow.

In spite of over four decades of effort to produce a cigarette that might be considered to be less hazardous, cigarette manufacturers are often criticized for not marketing "safe" products, even though public health authorities have generally taken the position that there is no such thing as a safe cigarette. For example, although the general tar reduction route received support from public health authorities in the U.S., the Federal Trade Commission is currently proposing to embark upon an educational campaign warning consumers that they should not consider low tar cigarettes to be a less risky option. When manufacturers have attempted to market novel products which might be regarded as less hazardous by others, these have failed to gain consumer acceptance and both public health and medical bodies have failed to accept these initiatives - in some instances openly criticizing them. This has occurred on more than one occasion in the U.S., most recently in the case of the launch of an alternative cigarette. Premier.

In addition to our continuing efforts to develop less hazardous products through our internal product modification research program, we are committed to sponsoring external research focused on filling the gaps in information that are needed to know what modifications could be made to cigarettes to reduce the risks.